5. 510(k) Summary

Date Prepared:

September 10, 2013

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, Connecticut 06902

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Contact: Jyh-Shyan Lin

OCT 2 5 2013

Device Trade Name:

ASPIRE Bellus / Mammography Viewer SMV658

Device Common Name:

Medical Image Processing and Analysis Software

Regulation Number:

21 CFR 892.2050

Device Classification:

Class II

Device Classification Name:

Picture Archiving and Communications System (PACS)

Panel:

Radiology

Product Code:

LLZ

Date Received:

TBD

Decision Date:

TBD

Decision:

TBD

Predicate Device:

- MammoWorkstation (K081630), Image Diagnostic International GmbH

Description of the Device

FUJIFILM's Mammography Viewer SMV658 (V3.0) system receives mammography images directly from FUJIFILM's digital mammography acquisition systems using DICOM protocol and PACS via network. These images are displayed on mammography diagnostic monitors for doctors' review. The SMV658 system works as mammography workstation depending on its configuration (monitors) and license information (software key). The system provides visualization and image enhancement tools (such as image review, measurement, post-processing, film printing, displaying mammography CAD results, and image manipulation) to assist the radiologists' review of mammography images for diagnostic and screening purposes.

Indication for Use

ASPIRE Bellus is intended to receive digital mammography images and to display these images on monitors for radiologists' review for diagnostic and screening purposes.

To assist radiologists, ASPIRE Bellus provides functions such as image review, measurement, post-processing, film printing, displaying mammography CAD results, and image manipulation.

ASPIRE Bellus does not accept lossy compressed mammographic images, which should not be used for primary diagnostic interpretation. Display monitors connected to ASPIRE Bellus for diagnostic interpretation of mammographic images must be cleared for use in digital mammography. All images sent to or imported into the ASPIRE Bellus must conform to regulatory requirements. Image quality must conform to applicable quality guidelines.

Technological Characteristics

The proposed Mammography Viewer SMV658 and the predicate device, MammoWorkstation (K081630), are medical application software running on Windows operating system installed on commercial general-purpose Windows-compatible computers. These devices are connected to mammography systems with DICOM standard and retrieve image data via network communications. These devices provide image visualization, enhancement, and manipulation tools for mammography images with various user interfaces and measurement tools for analysis of rendered images. Both the Mammography Viewer SMV658 and the predicate devices support the workflows, UI, and reporting functions for supporting the radiologists' review of mammography images for screening and diagnosis purposes.

Mammography Viewer SMV658 introduces no new safety or efficacy issues other than those already indentified with the predicate device. The results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of moderate concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices."

Testing

Mammography Viewer SMV658 is tested successfully with reference to its Software Requirements Specification, as well as design verification and validation documents and Traceability Matrix document. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the Mammography Viewer SMV658 software, which is found to be safe and effective and substantially equivalent to the currently-cleared predicate devices.

Testing involved system level functionality test, segmentation accuracy test, measurement accuracy test, interfacing test, usability test, serviceability test, labeling test, as well as the test for risk mitigation method analyzed and implemented in the risk management process. In addition, we conducted the bench performance testing using actual clinical images to help demonstrate that the proposed device achieved the expected accuracy performance.

Pass/Fail criteria were based on the requirements and intended use of the product. Test results showed that all tests successfully passed.

Conclusion

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 25, 2013

FUJIFILM Medical System U.S.A., Inc.
% Jyh-Shyan Lin, Ph.D.
Senior Manager, Regulatory, Quality and Clinical Affairs
419 West Avenue
STAMFORD CT 06902

Re: K132188
Trade/Device Name: Mammography viewer SMV658/ASPIRE Bellus
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 2, 2013
Received: October 4, 2013

Dear Dr. Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

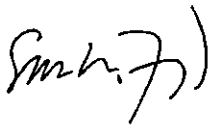
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132188

Device Name: ASPIRE Bellus/ Mammography Viewer SMV658

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K132188